



GP 1644

PATENT
Attorney Docket No. 4249.0002-05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
John B. SULLIVAN et al.)
Serial No. 08/405,454)
Filed: March 15, 1995)
For: ANTIVENOM COMPOSITION)
CONTAINING FAB FRAGMENTS)
(amended))

Group Art Unit: 1644
Examiner: Ron Schwadron, Ph.D.

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Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE AFTER FINAL

In response to the final Office Action of April 14, 1998 (Paper No. 33), Applicants submit the following remark.

Submission of Russell Declaration

Applicants file herewith the First Declaration of Findlay E. Russell, M.D., Ph.D. ("the First Russell Declaration") and the Second Declaration of Findlay E. Russell, M.D., Ph.D. ("the Second Russell Declaration"). These executed declarations have been revised from the unexecuted Russell declarations Applicants filed with the Amendment of December 19, 1997, in order to clarify their statements.

The Examiner indicated in Paper No. 33 that "[t]he Russell declaration will be fully considered upon receipt of a signed copy of said declaration. (Paper No. 33 at 2,

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last full paragraph; 4, first full paragraph; 4, third full paragraph; and 5, first full paragraph). Accordingly, Applicants respectfully request that the Examiner fully consider the Russell declarations.

Applicants respectfully submit that the Russell declarations are fully responsive to Paper No. 33. Nonetheless, Applicants will address some of the Examiner's comments in Paper No. 33.

**Rejection of Claims 40-42 Under
35 U.S.C. § 112, First Paragraph (Item 16)**

The Examiner rejected claims 40-42 under 35 U.S.C. § 112, first paragraph, because the term "antivenom" in claim 40 is allegedly not supported by an adequate written description in the specification. The Examiner indicated that the Russell declaration will be fully considered with regard to this rejection upon receipt of a signed copy of the declaration. Applicants respectfully submit that the First Russell Declaration is fully responsive to this rejection.

Although the Examiner did not fully consider the First Russell Declaration, the Examiner apparently considered Exhibit 4, which Applicants submitted with the First Russell Declaration. According to the Examiner, this reference indicates that the terms antivenin and antivenom are not interchangeable because the term antivenin can denote a non-immunoglobulin substance. Therefore, the Examiner concludes, the terms antivenom and antivenin are not interchangeable. Applicants respectfully submit, however, that interchangeability is not the test under 35 U.S.C. § 112, first paragraph.

Since the written description requirement is directed to "a person skilled in the art," 35 U.S.C. § 112, first paragraph, the specification need only convey to one skilled in the art that Applicant invented the claimed subject matter. Vas-Cath, Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). The written description requirement "does not require the claimed invention be described in the same words, i.e., *ipsis verbis*." Ex parte Yamaguchi, 16 U.S.P.Q.2d 1805, 1807 (PTO Bd. Pat. App. & Int. 1988); see also M.P.E.P. § 2063 ("The subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement."). Applicants respectfully submit that the specification would have conveyed to one skilled in the art that Applicants invented the claimed subject matter.

As Dr. Russell discusses in his first declaration, the specification specifically defines "antivenin" as a suspension of antibodies. (First Russell Declaration at ¶ 18). Although the term antivenin can be used to encompass non-immunoglobulin substances as well as immunoglobulin substances, Applicants expressly define "antivenin" in the specification as containing immunoglobulin substances. Accordingly, Applicants respectfully submit that the specification would have taught one skilled in the art that Applicants invented the claimed subject matter.

Furthermore, as Dr. Russell discusses in his first declaration, the very reference the Examiner relies upon as allegedly indicating that the terms antivenin and antivenom are not interchangeable actually teaches that these terms are interchangeable.

Dr. Russell, the author of this reference, states in his declaration that he indicated that

these terms are interchangeable when he listed them all together in the glossary to the reference when providing the single definition for antivenin, antivenene, anavenin, antivenimux, antiveninum, and antivenom. (First Russell Declaration at ¶ 18).

**Rejection of Claims 40-42 and 45-47 Under
35 U.S.C. § 112, First Paragraph (Item 17)**

The Examiner rejected claims 40-42 and 45-47 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not provide written description support for "essentially free from contaminating Fc". Specifically, the Examiner asserts that "the slight hint of a F(c) reaction disclosed in the specification does not support this recitation because 'essentially free from' requires that the Fc not be detectable." Applicants respectfully traverse this rejection, and Applicants respectfully submit that the Examiner has failed to consider the effect of the word "essentially" in this transitional phrase.

Just as "consisting essentially of" opens a claim to include elements that "do not materially affect the basic and novel characteristic" of the claimed invention, M.P.E.P. § 2111.03 (citing In re Hoechst, 190 U.S.P.Q. 461, 463 (C.C.P.A. 1976)), "essentially free from" opens the claim to materials that do not materially affect the basic and novel characteristics of the claimed invention. Thus, as in the 4-hour digest of Figure 4, the presence of minor amounts of contaminating Fc that did not materially affect the basic and novel characteristics of the claimed invention would fall within the claim. In other words, Fc may be present in detectable levels, but it may not be present in levels that

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

result in allergic reactions or serum sickness in general. See, e.g., Specification at 11, lines 11-29. Accordingly, Applicants respectfully request withdrawal of this rejection.

Request for Interview

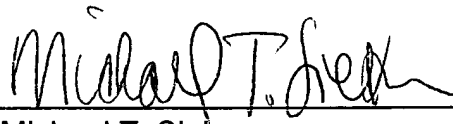
As Applicants have discussed above, Applicants respectfully submit that the First and Second Russell Declarations fully respond to Paper No. 33. Applicants respectfully request that the Examiner consider the declarations as he indicated he would in Paper No. 33, as well as the additional arguments contained herein. Applicants respectfully submit that the Russell Declarations and these arguments indicate that the claims are in condition for allowance.

If the Examiner does not agree, Applicants respectfully request that he contact the undersigned to resolve any remaining issues.

If any other fees are due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 
Michael T. Siekman
Reg. No. 36,276

Date: May 4, 1998